Remarks

This Amendment is in response to the Office Action dated **July 13, 2007.** Claims 1-27, 36 and 37 are pending in this application. The Office Action rejected claims 1-12, 14-27, 36 and 37 under 35 USC § 103 over Lee (US 5203777) in view of Tolkoff (US 5489277); and rejected claim 13 under 35 USC § 103 over Lee in view of Tolkoff further in view of Pacetti (US 6574497).

By this amendment, claim 37 is amended for clarification purposes only. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Claim Rejections

The rejections under 35 USC § 103 are traversed because the applied references do not teach all of the limitations of the pending claims, and because the rejections do not provide an actual motivation to modify the primary reference in a way that would result in a device meeting the limitations of the rejected claims.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings to produce the claimed invention. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See MPEP § 2142.

Independent claim 1 recites "a medical device and a marker wire…wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen." Independent claims 15 and 36 include similar recitations. Independent claim 37 requires a "rotational marker comprising a wire loop…wherein the rotational orientation of the wire loop may be determined using the imaging device."

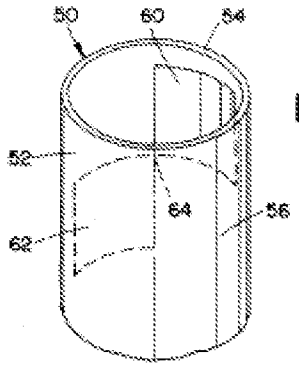

FIG. 2

Lee teaches a marking system having a first marker 60 and a second marker 62, wherein the markers 60, 62 are preferably rectangular in shape and made of metal, such as gold foil. See Figure 2, provided above, and column 5, lines 5-14.

The rejection states:

> Although Lee does not explicitly disclose that this metal is shaped into a wire, it is obvious to one skilled in the art to use wires as the marker on a medical device. This can be seen in Tolkoff, who teaches the uses of radiopaque metal markers in the shape of wires (col. 1, line 36-39).

See Office Action at page 3.

The rejection then asserts that it would have been obvious to replace the Lee markers 60, 62 with wire loops shaped according to the outer perimeter of the Lee markers 60, 62. See Office Action at page 3.

The assertion presented in the rejection is traversed. The text of Tolkoff cited in the rejection is located in the Background of the Invention section, wherein Tolkoff teaches that prior art markers on the outside of a tube can be "pre-formed metal rings or wire wrapped rings." See column 1, lines 36-39. Tolkoff then teaches that such prior art markers create an undesirable enlarged region that can catch on bodily tissues. See column 1, lines 42-46.

Tolkoff further teaches away from wire markers by discussing disadvantages associated with wire. For example, Tolkoff teaches that "the end of the wire is typically sharp and has to be finished to prevent harm to the patient," and that a wire may spring back to its original orientation, "causing it to enlarge or even come loose." See column 1, lines 63-67.

Tolkoff then teaches its inventive device, which includes a marker ring 20 oriented within the tube 10. See e.g. Figure 4, provided below.

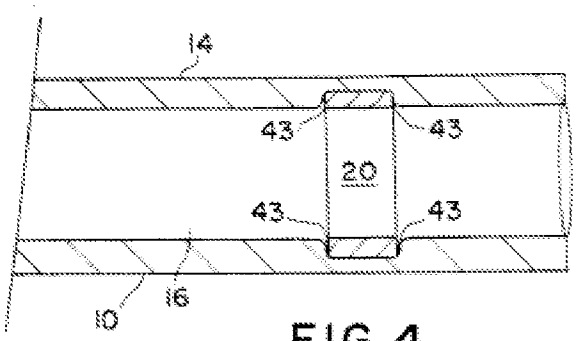

FIG. 4

The rejection does not provide an actual motivation to replace the Lee markers with wire. There is no prior art teaching that wire would be desirable for use as an alternative to the Lee foil markers.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Prior art references must be considered as a whole and suggest the desirability, and thus the obviousness, of making the combination. See *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.,* 221 USPQ 481 488 (Fed. Cir. 1984).

The mere existence of a "wire wrapped ring" oriented around a tube, as disclosed by Tolkoff in the Background of the Invention section, does not provide a motivation to modify Lee. When Tolkoff is considered as a whole, there is absolutely no motivation to replace the Lee foil markers with wire because Tolkoff teaches away from wire markers and leads the reader toward a non-wire alternative.

Further, Lee teaches that an advantage of the Lee invention "is the provision of a marker system which has maximum visibility in a fluoroscopic or X-ray film image." See column 3, lines 27-29. Thus, Lee suggests that the preferred foil embodiment provides maximum visibility. A person of ordinary skill in the art would recognize that modification of the Lee marker in a way that would meet the limitations of the rejected claims could reduce visibility of the device under fluoroscopy, making the modified device less suitable for its intended use than the original Lee device, or even unsuitable for its intended use altogether. Therefore, Applicant asserts that there is no prior art motivation to perform the modification proposed in the rejection.

Neither Lee nor Tolkoff discloses or suggests a "marker wire…wherein the

rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen" as recited in claim 1, and similarly recited in claims 15 and 36. Neither Lee nor Tolkoff discloses or suggests a "rotational marker comprising a wire loop…wherein the rotational orientation of the wire loop may be determined using the imaging device," as recited in claim 37. Thus, the applied references do not disclose or suggest all of the limitations of the rejected claims.

Therefore, Applicant asserts that the rejection does not establish a *prima facie* case of unpatentability under 35 USC § 103 against independent claims 1, 15, 36 or 37. Each pending dependent claim is patentable over the applied references for at least the reasons discussed with respect to the independent claim from which it depends.

Pacetti was cited against dependent claim 13 for its teachings relevant to MRI markers. See Office Action at page 4. The addition of Pacetti does not remedy the shortcomings of the rejection discussed above. Pacetti does not provide any motivation to modify Lee or Tolkoff in a way that would arrive at a modified device meeting the limitations of the rejected claims.

Accordingly, Applicant requests withdrawal of the rejections under 35 USC § 103.

Conclusion

Based on at least the foregoing amendments and remarks, Applicant respectfully submits this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-27, 36 and 37 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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